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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
109/724,797	11/28/2000	Jon S. Thorson	2653/40	7811
26646	7590	02/07/2003		
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			EXAMINER	
			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/724,797	THORSON, JON S.
	Examiner Daniel M Sullivan	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 21 November 2002.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 9,88-96,98,99,145 and 150-156 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 9,88-96,98,99,145,150 and 151 is/are allowed.  
 6) Claim(s) 152-156 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 21 Noveber 2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a)  The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) ✓  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

This Office Action is a response to the “Amendment under 37 CFR 1.115” filed 21 November 2002 (Paper No. 16) in reply to the Non-Final Office Action mailed 30 July 2002 (Paper No. 13). Claims 1-9, 57, 58, 88-99, 145, 146 and 148 were considered in Paper No. 13. Claims 9, 88, 89, 91, 95, 96, 98, 99 and 145 were amended, claims 150-156 were added and claims 1-8, 57, 58, 97, 100, 101, 142-144, 146, 148 and 149 were canceled in Paper No. 16. Claims 9, 88-96, 98, 99, 145 and 150-156 are pending and under consideration.

### *Response to Amendment*

#### Drawings

The corrected or substitute drawings were received on 21 November 2002. These drawings are acceptable subject to correction of the informalities indicated on the attached “Notice of Draftperson’s Patent Drawing Review,” PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

#### Specification

The objection to the specification is withdrawn.

#### Claim Rejections - 35 USC § 101 and 112

Rejection of claims 9, 88-96 and 145 under 35 U.S.C. § 101 and 112, first paragraph, is withdrawn in view of the arguments of record in Paper No. 16. Applicant argues persuasively

that the disclosed polypeptide comprising the sequence set forth as SEQ ID NO:36 would function as a P450 oxidase in the calicheamicin synthesis pathway and as such would have specific, substantial and credible utility.

Rejection of claims 9, 88-96 and 145 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Rejection of claim 6 under 35 U.S.C. § 102 as anticipated by the prior art is rendered moot by the cancellation of the claim in Paper No. 16. Newly added claims 50-56 are free of the art of record.

New Grounds Necessitated by Amendment

*Claim Rejections - 35 USC § 112, enablement*

New claims 152-156 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the polypeptide sequence set forth in the instant application as SEQ ID NO:36 and having the function of a P450 oxidase, does not reasonably provide enablement for any nucleic acid molecule that does not encode the polypeptide sequence set forth as SEQ ID NO:36. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 152-156 are directed to nucleic acid molecules having various degrees of similarity with the nucleic acid molecule set forth as SEQ ID NO:35 based on hybridization or sequence alignment. Further, although it seems that Applicant intends that the claimed nucleic acids comprise sequence that is homologous to SEQ ID NO:35, because claim 9 is directed to a nucleic acid comprising SEQ ID NO:35 and the nucleic acid of the claims need only be homologous to a “corresponding portion” of the nucleic acid of claim 9, the claimed sequence need not have any homology with SEQ ID NO:35 at all. That is, the claims encompass a nucleic acid that is homologous to the portion of the nucleic acid of claim 9 that is outside of the described portion of the nucleic acid (i.e. SEQ ID NO:35). As it seems that applicant intends that the claims be limited to nucleic acids comprising sequence having the recited similarity to SEQ ID NO:35, the arguments below will be directed to that more limited scope.

The claims encompass a genus of nucleic acid molecules having the structural limitation of hybridizing under high stringency to SEQ ID NO:35 or 60%, 70%, 80% and 90% to SEQ ID NO:35. However, the claimed nucleic acids need not have any function. Therefore the claims encompass a large genus of nucleic acid molecules, of which the vast majority would have no known function. The instant disclosure teaches only a nucleic acid encoding the amino acid sequence of SEQ ID NO:36 and the likely function of the protein encoded by SEQ ID NO:36. Clearly, the specification and prior art would not enable the skilled artisan to use any nucleic acid having even 90% homology to SEQ ID NO:35, wherein said nucleic acid does not encode a functional protein. Further, as the teachings in the specification only contemplate a nucleic acid having the function of a CalS gene, the disclosure is not enabling for any nucleic acid encoding a polypeptide or P450 oxidase that does not have the same function as the CalS gene product.

Finally, given the unpredictability of protein function based on structure alone (see Paper No. 13, the paragraph bridging pages 6 and 7) and the complete absence of teachings in the disclosure regarding the functional requirements of the CalS gene product, the skilled artisan would not be able to identify nucleic acid sequences encoding polypeptides having the function of the CalS gene product, other than those having the sequence set forth as SEQ ID NO:35, without engaging in trial and error experimentation to synthesize and test every amino acid combination encompassed by the claims for CalS activity. Thus, using the full scope of even a relatively narrow embodiment of the claims would require the skilled artisan to synthesize and test thousands or millions of polypeptides to identify those polypeptides having the same activity as the claimed polypeptide. This would clearly require undue experimentation because neither the specification nor the prior art provide teachings that would enable the skilled artisan to narrow the candidate polypeptides to a manageable scope, and the instant disclosure does not describe an assay for CalS gene product activity that would allow for the rapid screening of candidate polypeptides.

Applicant's arguments in response to rejection of claims under 35 U.S.C. § 112, first paragraph, as lacking enablement are directed to the credibility of the asserted function of the polypeptide encoded by SEQ ID NO:35. As indicated above, Applicant's arguments are found persuasive insofar as the claims are directed to a nucleic acid encoding SEQ ID NO:36. However, for reasons of record in Paper No. 13 and herein above, the disclosure is would not enable the skilled artisan to use any and all nucleic acid of claims 152-156 without engaging in undue experimentation.

*Claim Rejections - 35 USC § 112, possession*

Claims 152-156 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection of claim 6 in Paper No. 13, Applicant has limited the new claims to those that hybridize under high stringency to the nucleic acid of claim 9, or having a specified sequence homology to the nucleic acid of claim 9. Again, it is noted that the claims, as they are directed to nucleic acids having similarity to any portion of a nucleic acid comprising SEQ ID NO:35, are not limited to a sequence having any similarity to SEQ ID NO:35 at all. The discussion below assumes that applicant intends that the claims be directed to nucleic acids comprising sequence that is similar to that set forth as SEQ ID NO:35.

With regard to claim 152, Applicant argues that the claimed subject matter is adequately described because hybridization under high stringency would limit the nucleic acids to those that are highly similar in structure to the nucleic acid of claim 9. However, as stated in the previous office action, “[i]t is not at all clear that every sequence that hybridizes with SEQ ID NO:35 [under any conditions] has an activity similar to that of SEQ ID NO:35...it is not apparent that Applicant’s disclosure adequately sets forth sufficient structure/function information to describe nucleic acids that have activity similar to that of SEQ ID NO:35” (paragraph bridging pages 10 and 11 in Paper No. 13, emphasis added). Likewise, it is not apparent that every nucleic acid having 90% sequence identity to SEQ ID NO:35 is functionally the same. Therefore, for reasons

of record in Paper No. 13, the new claims 152-156 are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description.

***Allowable Subject Matter***

Claims 9, 88-96, 98, 99, 145, 150 and 151 are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
February 3, 2003



JAMES KETTER  
PRIMARY EXAMINER

**Attachment for PTO-948 (Rev. 03/01, or earlier)**

**6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

06/01/01